

FreshAir Sensor LLC Financial Conflict of Interest Policy

Revision Date: 19-Apr-2021

Purpose

This policy documents the application and requirements of the company policy with regard to identifying and managing financial conflicts of interest. This policy protects the integrity of the company and complies with the federal regulations. These regulations are contained in the 2011 Revised Financial Conflict of Interest (FCOI) Regulation Promoting Objectivity in Research found in 42 CFR Part 50 Subpart F. Effective immediately, each investigator affiliated with FreshAir Sensor by an NIH or other applicable grant or contract, must be in compliance with 42 CFR Part 50 Subpart F. These regulations fulfill the commitment to unbiased research and high ethical standards. The following are the terms relevant to the policy.

Investigator

Investigator is defined as any person, (including collaborators of any type), responsible for design, conduct or reporting of research funded by NIH or any other applicable grant or contract.

Training

All investigators, including FreshAir Sensor collaborators, are required to complete training related to Financial Conflict of Interest. If any significant financial conflicts are determined, they must be disclosed immediately. Training must be updated regularly (no less than every four years).

NIH resources are available at <http://grants.nih.gov/grants/policy/coi/tutorial/2011/fcoi.html>.

Significant Financial Interest (SFI)

1. SFI is defined as financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's spouse and dependent children) that appears to be reasonably related to the investigator's institutional responsibilities:
 - With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000;
 - With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remunerations from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interests (e.g., stock, stock options, or other ownership interest) or
 - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. Investigators must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available) related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state or local government agency, an

institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, medical center, or research institute that is affiliated with an Institution of higher education. The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the NIH-funded or other applicable research.

3. The term significant financial interest does not include the following types of financial interests:
 - Salaries, royalties or other remuneration paid by the institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
 - Any ownership interest in the Institution held by the investigator, if the Institution is a commercial or for profit organization;
 - Income from investment vehicles, such as mutual funds and retirements accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
 - Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, research institute that is affiliated with an Institution of higher education;
 - Income from service on advisory committees or review panels for a federal, state or local government agency an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

FCOI

A financial conflict of interest exists when the FreshAir Sensor compliance officer reasonably determines that a SFI as defined in previous paragraphs could affect the design and/or conduct of NIH-funded research.

FCOI Management

Actions to address the FCOI are meant to ensure, as much as possible, that the design, conduct and reporting of research will be bias-free.

Disclosures and Reporting

The designated compliance official(s) will review disclosures to evaluate whether they contain a FCOI. If no FCOI is found, the disclosures will be filed in the SFI folder. If a FCOI is identified, it will be included in the FCOI report through the eRA Commons prior to expending funds. If any interests are identified as conflicting after the initial disclosure, they must be reported within 30 days. FreshAir Sensor will then report it to NIH within 60 days. Each investigator must submit an updated disclosure of a SFI not less than annually.

Records Management

The records of all disclosures and all actions taken by FreshAir Sensor as a result of those disclosures will be maintained for at least three years from the date of submission of the final expenditures report for the given NIH-sponsored research.

Compliance and Penalties for Non-Performance

If it is determined that an investigator failed to comply with FreshAir Sensor's FCOI policy, FreshAir Sensor shall complete a retrospective review of the investigator's research within 120 days activities to determine the possibility of bias. If a bias is found, FreshAir Sensor shall act in accordance with policy and, as well, submit a mitigation report to the NIH, in accordance with 42 CFR 50.605(b)(3). This report will address the impact of bias on the research project and the actions taken to mitigate the bias. FreshAir Sensor will work with the Investigator to set up an FCOI management plan to mitigate the situation. In extreme cases of bias, the Investigator may lose the right to work on the project or any role in future NIH funded research.

Research

By definition, NIH research is any project governed by PHS regulation, but excluding applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

Point of Contact

If you have a conflict of interest or if you have a question to discuss, contact the FreshAir Sensor Signing Official, Joseph BelBruno.